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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,911	10/06/2000	Steven M. Tracy	UNMC 63124	5961

23377 7590 10/14/2005
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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,911

Applicant(s)

TRACY ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,10-15 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,10-15 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, examiner Mosher.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/2004 and 7/8/2004 has been entered.

Claim Rejections - 35 USC § 112

Claims 1, 10-15, 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the full scope of the invention as claimed. This is a "written description" rejection.

The claims are drawn to the genus of coxsackie virus genomes which are attenuated and which also have a pol modification that increases fidelity and decreases reversion of the attenuating phenotype. The genome modifications are described in the claims solely by function. The specification provides limited guidance on the specific

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modifications which produce the desired functions. In regard to attenuation, the specification discusses with particularity modification of the 5' nontranslated region, modifying position 232, 234, 236, or 232-236. In regard to polymerase modification, the specification discusses with particularity modification of 3D amino acid 328 (nucleotides 6893-6895) in CVB3, and also modification of amino acids 327, 194, and 213. There is not a well-established relationship between polymerase structure and fidelity in the coxsackie virus art, or a well-established relationship between attenuation and the full spectrum of possible alterations to the coxsackie virus genome. Jablonski et al (Journal of Virology 65: 4564-4572, 1991) is cited as evidence that even modifications as similar as alanine or valine at a single location have distinctly different effects on polymerase activity for a related virus, indicating a high level of unpredictability in this art.

There are no species of the claimed invention reduced to practice, and no demonstration of the increased fidelity required by the claims. The specification provides assays by which fidelity could be tested; however, possession of an assay method does not confer possession of the products that could potentially be identified using the assay. For these reasons, the specification as a whole does not reasonably convey that applicants possessed the invention as claimed, and certainly does not reasonably convey that applicants possessed the full scope of the attenuating modifications and the full scope of the fidelity modifications required for the invention as broadly claimed.

The following references (not available as prior art) are cited as of interest in illustrating the unpredictable effects of structural modification on polymerase function in

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coxsackie and related viruses, and the unpredictable effects of polymerase modification on other viral functions and on viral viability: Bell et al, Journal of Virology 73:9413-9421, 1999; Parsley et al, Journal of Biological Chemistry 274:12867-12876, 1999; Cornell et al, Journal of Virology 78:4397-4407, 2004; Cornell et al, Journal of Virology 78:13007-13018, 2004; Cornell et al, Virology 298:200-213, 2002; Gohara et al, Journal of Biological Chemistry 275:25523-25532, 2000.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Mary Mosher".

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER